GALEO Hydro Coronary Guide Wire
Add to File for the Special 510(k) Notification

1. 510(K) SUMMARY

Name and Address of Sponsor:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:		
	Proprietary Name	GALEO Hydro Guide Wire
	Classification	Class II (21 CFR 870.1330)
	Classification Name	Catheter Guide Wire
	Product Code	DQX
	510(K) Number	K001736

General Description and Predicate Devices:

BIOTRONIK's GALEO Hydro family of guide wires includes coronary steerable guide wires with various tip flexibilities and configurations that are intended to guide the placement of intravascular catheters with compatible guide wire lumens during PTCA or other therapeutic or diagnostic procedures. The GALEO Hydro guide wires are substantially equivalent to BIOTRONIK's GALEO Guide Wires (#K982272, cleared January 8, 1999). The GALEO Hydro Guide Wires are identical in design and materials and functionally equivalent to the GALEO Guide Wire already cleared for distribution, with the exception of the most distal 12 cm section of the guide wire has been coated with a hydrophilic coating. This hydrophilic coating aids in the insertion of the guide wire into the coronary vascular system. The predicate device for the hydro-coating is a catheter stylet manufactured by TFX Medical (K992664, cleared 04/13/00) that is coated with the same hydrophilic top coating, Slipskin®.

Indications for Use:

Galeo Hydro coronary guide wires are indicated to facilitate the placement of balloon dilation catheters or other interventional devices with compatible guide wire lumen during an interventional procedure.

Name and Address of Manufacturing Site:
BIOTRONIK GmbH & Co.
Woermannkehre 1, Berlin, Germany
011-49-30-689-05-304

Manufacturer Temporary Registration No.: 9018831

Contact Person(s) and Phone Number:
Jon Brumbaugh
Director of Regulatory Affairs
Phone (888) 345-0374
Fax: (503) 635-9936

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2000

Mr. Jon Brumbaugh
Director of Regulatory Affairs
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Re: K001736
Trade Name: GALEO Hydro Guide Wire
Regulatory Class: II (two)
Product Code: DQX
Dated: July 14, 2000
Received: July 17, 2000

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

Galeo Hydro coronary guide wires are indicated to facilitate the placement of balloon dilation catheters or other interventional devices with compatible guide wire lumen during an interventional procedure.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001736/S1